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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,064	09/25/2003	Lars Hojlund Christensen	6535.200-US	5846

23650 7590 09/14/2005

NOVO NORDISK, INC.  
PATENT DEPARTMENT  
100 COLLEGE ROAD WEST  
PRINCETON, NJ 08540

EXAMINER
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FORTUNA, ANA M

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/671,064

Applicant(s)

CHRISTENSEN ET AL.

Examiner

Ana M. Fortuna

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 11, 16, and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mannweiler et al (US Patent 5,508,196)(hereinafter 'patent 196). Patent '196 discloses filtering a stream containing a product from a fermentation process through a microfiltration membrane at a temperature of at least 70 degree C. (abstract, column 1, lines 1-31, and 42-57, and column 2, lines 1-25). Regarding claim 2, the process is performed without the presence of activated carbon. As to claims 3-4, the temperature is discussed above. Regarding claim 5, the membrane performs in a cross-flow mode (see figure, element 12). As to claim 11, the process is performed continuously, and with fluid recirculation (column 1, lines 42-47, column 2, lines 34-68, column 3, lines 1-18). Regarding claim 16, a precipitation step is also performed, e.g. precipitation by centrifugation (column 2, lines 42-43). As to claims 17-20, the product e.g. permeate, of patent '196, depending on the selected temperature of the feed e.g. higher than 70 degree C, should be or inherently is at a temperature of 70 or higher at the exit of the filtration process, and is further cooled down when immediately recycled back with the feed in the reactor

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 5, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17-20, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laustsen et al (US Patent

6,582,606)(hereinafter patent '606) in view of Weiss et al (US Patent 5,453,200)(hereinafter patent 200).

Patent '606 discloses microfiltration of fermentation derived products at temperature of 65 degree C, by microfiltration, or combination of microfiltration and ultrafiltration membranes (abstract, column 2. lines 6-30, and column 5, lines 4-8). Performing the filtration a temperature of 66 degree C is not disclosed in patent '196.

Patent '200 discloses purification of fermentation broth containing proteins including purification by membrane filtration, and protein evaporation at 80 degree C. The later teaching suggests that the proteins are heat resistant to heat penetration at 80-degree C., e.g. proteases, amylases, cellulases, etc (column 7., claim 3, abstract, column 4, second paragraph, and column 6, line 24). It would have been obvious to one skilled in the art at the time the invention was made to perform a filtration of treatment as disclosed in patent '606, for a broth containing cellulases (column 3, lines 49-50), at a temperature higher than 65 degrees C, based on the teaching of patent '200, e.g. the heat resistant properties of cellulases, since increase of one temperature grade does not appear to be significant to denature the protein from the broth. The temperature can be further increased at values higher than 66, e.g. lower than 80 degree C. based on membrane material resistant to temperature.

As to claim 2, using activated carbon is alternative depending on whether color or other impurities are desire to be removed from the broth prior or together with filtration.

Reference '200 teaches purification of fermentation by microfiltration/ultrafiltration and without activated carbon as conventional (column 4, lines 4-26).

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Regarding claims 8-12, the membrane materials and batch and continuous process are disclosed in '606 (column 5, lines 4-12, and column 6, second paragraph). Regarding claims 13-15, a membrane with molecular weight lower than the molecular weight of the fermentation product is all what is needed for its retention, one skilled in the art at the time the invention was made can expect its retention by membranes with molecular weight cut-off lower than the required, which further retain additional components with the selected molecular weight.

As to claims 17-20, the retained product should be at the fed temperature during the process, e.g. 65 degree C, for the filtration period, for the selected operating time in either batch or continuous process. Regarding claims 21-22, 24, protein is discussed above.

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mannweiler et al (US Patent 5,508,196)(hereinafter 'patent 196) as applied to claim 5 above, and further in view of Rochilgo (US Patent 5,143,630). Patent '196 fails to disclose vibrating the membrane. Rochilgo teaches membranes suitable for separation of components from a fermentation process, the filter operation includes vibration, e.g. by rotation (abstract, column 12, lines 53-68). It would have been obvious to one skilled in the art at the time the invention was made to perform the filtration of patent '196 in combination with vibration as suggested in Rochilgo, or conventional vibration means, e.g. ultrasonic vibration application, for maintaining the membrane surface clean during the process.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mannweiler et al (US Patent 5,508,196)(hereinafter 'patent 196) as applied to claim 1 above, and further in view of Hussain (6,814,862). Patent '196 fails to disclose the cleaning process or back pulse (backsock). Cleaning membrane deposited solids periodic reversal of permeate is known in the art as evidenced by Hussain (column 4, lines 13-24). It would have been obvious to one skilled in the art at the time the invention was made to clean the membrane, either Microfiltration or ultrafiltration by reversing the flow under pressure, e.g. back wash, or backpulse, as suggested in 'Hussain.

***Allowable Subject Matter***

6. Claims 23, 25-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: treatment of the particular proteins under the claimed temperature conditions is not disclosed or suggested in the prior art of record.

***Conclusion***

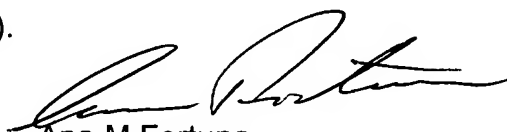
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Additionally cited prior art teaches membrane filtration of fermentation broth with microfiltration and optional ultrafiltration and combination with

centrifugation as conventional, with the operating temperature conditions depending on the particular composition of the broth.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ana M Fortuna  
Primary Examiner  
Art Unit 1723

AF  
September 06, 2005



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